K003400

MAY 1 0 2001

510(k) Summary - CRP US on Roche / Hitachi Family of Clinical Analyzers

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576 3723

Contact person: Priscilla A Hamill

Date prepared: October 27, 2000

Device Name

Proprietary name: CRP US Test System

Common name: C-Reactive Protein test

Classification name: System, Test, C-Reactive Protein

Device description

The C-Reactive Protein US test is a latex particle-enhanced immunoturbidimetric assay packaged for use on the Roche/Hitachi family of analyzers.

Intended use

For the quantitative determination of C-reactive protein in human serum and plasma.

Indication for use

The C-reactive protein test is used for the detection and assessment of inflammatory disorders, tissue injury and infection.

Substantial equivalence

The CRP US test is equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Integra C-Reactive Protein test (K981897).

510(k) Summary - CRP US on Roche / Hitachi Family of Clinical Analyzers, continued

Substantial equivalence - similarities

The following table compares CRP US, with the predicate devices.

Feature	New Device CRP US	Predicate Device Roche Integra Cassette (K981897)
Intended use	For the quantitative determination of C-reactive protein	For the quantitative determination of C-reactive protein
Indication for use	Detection and assessment of inflammatory disorders, tissue injury and infection.	Detection and assessment of inflammatory disorders, tissue injury and infection.
Sample type	Human serum and plasma	Human serum and plasma
Traceability	IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619)	IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619)

Substantial equivalence – differences

The following table compares the CRP US, with the predicate devices.

Feature	New Device CRP US	Predicate Device Roche Integra Cassette (K981897)
Assay principle	Latex particle - enhanced immunoturbidimetric test	Latex particle - enhanced immunoturbidimetric test
Instrument	Roche/Hitachi family of analyzers	Integra family of analyzers

Substantial equivalence – performance characteristics

The performance characteristics of the CRP US were evaluated and found to be equivalent to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 0 2001

Ms. Priscilla A. Hamill
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: 510(k) Number: K003400
Trade/Device Name: CRP HS Test System
Regulation Number: 866.5270
Regulatory Class: II
Product Code: DCN
Dated: October 27, 2000
Received: November 1, 2000

Dear Ms. Hamill:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A K003400

Device Name: CRP US Test System

Indications For Use:

For the quantitative determination of C-reactive protein in human serum and plasma. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases.

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003400

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)